

DATE OUT:_____

DP BARCODE: D172884 SUBMISSION: S409362 REG CASE #: 030016
CHEMICAL CODE/NAME: 088502 Zinc Oxide (Chemonite Part C)

REGISTRATION DIVISION/REGISTRATION SUPPORT BRANCH/PRODUCT
CHEMISTRY REVIEW SECTION TRANSMITTAL/PRODUCT CHEMISTRY DATA
REVIEW IN SUPPORT OF REGISTRATION []/AMENDMENT [X]/ME-TOO []
OR REREGISTRATION [] OF A TECHNICAL/MANUFACTURING-USE PRODUCT

Data Submitter: 003098 Baxter J.H. & Company

MRID #'s: 421265-00, to 421265-03 EPA Received Date: 12/10/91

PM#/NAME: 21 Susan Lewis Phone #: 305-6900
CRM NAME: Sidney Jackson Phone #: 305-7610

INTRODUCTION

The registrant is requesting a label amendment to change the percentage of the active ingredient, zinc oxide, from the previously approved, 99% to the proposed 97% on the label. There was no cover letter with this request, however, information from the product's jacket indicated a registered label, dated 09/05/84, in which the active ingredient, zinc oxide, was listed at 99%. The CSF showed a non-registered zinc oxide with a Reg. No. 3098-RI, dated 10/05/83.

Certification of ingredient limits, a requirement of GLR #'s 62-2 was included with this submission (MRID #421265-02) showing minimum zinc oxide concentration at 93% and a typical concentration of 97%. The balance of 3% was reported as impurities. The equivalent of metal zinc was reported at a minimum of 75% and a maximum of 78%.

DATA GAPS

Sample analysis, a requirement of GLR #62-1 and a CSF were not submitted.

CONCLUSIONS/RECOMMENDATIONS

1. At this time, we are unable to conclude if the magnitude of the active ingredient of 97% for zinc oxide represents the nominal concentration that should be reported on the label as per PR Notice 91-2.

2. For approval of zinc oxide label amendment (Reg. No. 3098-18) requested in this submission, the registrant will need to submit sample analysis, a requirement of GLR #62-1 and a CSF to ensure that label amendment conform with PR Notice 91-2 pertaining to the nominal concentration.
3. The accompanying data package should be rerouted to SRRD, c/o Mark Wilhite, to be submitted to us for review as part of the product chemistry data requirements for reregistration of Baxter J H & Company's chemical 088502 Zinc oxide, Case #4099, CAS #1314-31-2. The previous reregistration review of this chemical was completed on 1/12/92 (S. Malak, D171058).

<u><i>Sami Malak</i></u> Reviewer: Sami Malak, Chemist	<u>06/02/93</u> Date
<u><i>H. Podall</i></u> Section Head: Harold Podall, Ph.D.	<u>06/2/93</u> Date

PCRS Comments

We have no objections to the changes in the magnitude of the technical grade active ingredient, zinc oxide, from the previously approved, 97% (CSF, dated 00/00/00), to the proposed 97%

The accompanying data package should be rerouted to SRRD, c/o Mark Wilhite, to be submitted to us for review as part of the product chemistry data requirements for reregistration of Baxter J H & Company's chemical 088502 Zinc oxide, Case #4099, CAS #1314-31-2. The previous reregistration review of this chemical was completed on 1/12/92 (S. Malak, D171058).

Reviewer: Sami Malak, Chemist

Approved by: Harold Podall, Head